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10/823,906	04/14/2004	David E. Clarke	30754/39959	6103

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,906	CLARKE, DAVID E.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *17 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-18 are pending in the application and are being examined on the merits herein.

Election/Restrictions

1. During a telephone conversation with Applicant's representative, Katherine Neville, on August 13, 2007 a provisional election was made without traverse to prosecute the invention of Group I, a method for treating ulcerative colitis, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. A telephone call to the Applicants representative, Katherine Neville, on August 13, 2007 was placed for an election of species of: (1) a nicotinic compound that is selected from nicotine, an analog of nicotine, and nicotine antagonist; (2) an anti-depressant; (3) an additional ulcerative colitis treatment. Applicants have elected without traverse: (1) nicotine as the species of a nicotinic compound; (2) bupropion as the species of an anti-depressant; and (3) budesonide as the species of an additional ulcerative colitis treatment. Affirmation of this election must be made by applicant in replying to this Office action.

Accordingly, claims 1-16 are examined on the merits herein.

The restriction requirement and the election of species requirement are made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on May 17, 2006 is acknowledged.

Specification

3. The use of the trademarks ZYBAN®, WELLBUTRIN®, and Colazal™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of a pharmaceutical composition comprising a combination of nicotine and bupropion, does not reasonably provide enablement for administration of a pharmaceutical composition comprising a combination of any analog of nicotine or any nicotine antagonist and any anti-depressant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to the administration of a pharmaceutical composition comprising a combination of nicotine, an analog thereof or a nicotine antagonist and an anti-depressant.

(2). ***State of the Prior Art***:

The skilled artisan would view that the administeration of a pharmaceutical composition comprising a combination of any nicotine analog or any nicotine antagonist and any anti-depressant is highly unlikely.

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the arts of ulcerative colitis and smoking cessation are

extremely high.

(4). ***Predictability of the Art***:

The administeration of a pharmaceutical composition comprising a combination of any nicotine analog or any nicotine antagonist and any anti-depressant is highly unpredictable. In fact, nicotine analogs, nicotine antagonists, and anti-depressants have different structures and thus different chemical and physical properties and efficacies. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the administration of a pharmaceutical composition comprising a combination of nicotine, an analog thereof or a nicotine antagonist and an anti-depressant.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the administration of a pharmaceutical composition comprising a combination of any analog of nicotine or any nicotine antagonist and any anti-depressant is limited.

The disclosure of the administration of a pharmaceutical composition comprising a combination of nicotine and bupropion is adequate (examples 1-2, pages 22-26).

(7). ***Working Examples***:

The working examples in the specification show treatment of colitis with a nicotine-bupropion patch (example 1, pages 22-24). The working examples in the specification also show the use of a nicotine-bupropion patch as a long-term substitute for smoking (example 2, pages 24-26). Thus, the working examples show the administration of a pharmaceutical composition comprising nicotine and bupropion, not administration of a pharmaceutical composition comprising any analog of nicotine or any nicotine antagonist and any anti-depressant.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of the administration of a pharmaceutical combination comprising any analog of nicotine or any nicotine antagonist and any anti-depressant. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (US 6,344,222) in view of McCullough et al. (US 6,495,605) as evidenced by Eswara et al. (US 5,780,051), and in further view of Hanauer (Gut, 2002, Vol. 51, pp. 182-183).

Cherukuri et al. teach a nicotine chewing gum delivery system for smoking reduction or cessation (abstract and column 17, line 54). The invention of Cherukuri et al. can also be utilized for treatment of ulcerative colitis because studies have demonstrated nicotine therapy have benefited ulcerative colitis patients (column 17, lines 57-59). The nicotine composition of Cherukuri et al. is administered orally (column 23, line 44). The concentration of nicotine is from about 0.1 to 10 mg (column 11, line 20).

Cherukuri et al. do not teach combination with either bupropion or budesonide in the treatment of ulcerative colitis or as a substitute for smoking. Furthermore, Cherukuri et al. do not teach transdermal administration.

McCullough et al. teach methods and compositions for smoking and nicotine addiction comprising bupropion (abstract). Bupropion is given from about 10 to about 750 mg per day (column 9, lines 47-48). The treatment period of bupropion is from 2 weeks to 6 months (column 9, lines 60-61). Bupropion composition is administered orally or transdermally (column 10, lines 28-29).

As evidenced by Eswara et al., bupropion is a sensory altering nicotine substitute (column 4, lines 62-63; and column 5, lines 5 and 11).

Hanauer teaches a method for treating ulcerative colitis comprising administering budesonide (page 182).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the pharmaceutical composition of Cherukuri et al. to include bupropion and budesonide because the compounds of McCullough et al. and Hanauer disclose bupropion and budesonide and according to McCullough et al. and Hanauer, bupropion can be used in smoking cessation and budesonide can be used to treat ulcerative colitis.

The motivation to combine the pharmaceutical composition of Cherukuri et al. to the compositions of McCullough et al. and Hanauer is that the compounds of McCullough et al. and Hanauer are bupropion and budesonide and bupropion and budesonide can be used in smoking cessation and as a treatment for ulcerative colitis.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding six months or a year as recited in instant claims 7 and 12-13, McCullough et al. teach the treatment period of bupropion is from 2 weeks to 6 months, which meets the limitations of the instant claims (column 9, lines 60-61). It is considered that one of ordinary

skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the treatment time period of the bupropion provided in a pharmaceutical composition, according to the guidance set forth in McCullough et al., to provide a pharmaceutical composition having the desired treatment time period of the bupropion. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding dose range of nicotine and bupropion as recited in instant claims 14-16, Cherukuri et al. teach the concentration of nicotine is from about 0.1 to 10 mg (column 11, line 20) and McCullough et al. teach the dose of bupropion ranges from about 10 to about 750 mg per day (column 9, lines 47-48), which meets the limitations of the instant claims. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the dose of nicotine and bupropion provided in a pharmaceutical composition, according to the guidance set forth in Cherukuri et al. and McCullough et al., to provide a pharmaceutical composition having the desired dose of nicotine and bupropion. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Conclusion

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

S. Wang
SHENGJUN WANG
PRIMARY EXAMINER